# Transporting and Shipping Infectious Substances and Diagnostic Specimens (Updated January 2, 2006)

Patient specimens and infectious substances <u>must be properly packaged and labeled to protect the employees transporting and receiving the materials.</u>

A few types of materials sent for diagnostic testing, such as pap smears and newborn screening blood spots, have unique properties and do not ship under the full requirements of most diagnostic specimens. To ship pap smears or newborn screening blood spots follow the information below.

## **Shipping Fixed Microscope Slides and Newborn Screening Blood Spots**

#### **Shipping Microscope slides:**

Once pap smear slides are fixed, the slides are no longer considered infectious and do not meet the definition of an infectious material. To ship microscope slides, take the following steps:

- 1. Place slides into the cardboard slide holder.
- 2. Wrap the lab form around the closed slide holder and secure with a rubber band around the slide holder and lab form.
- 3. Place the slide holder in a manila envelope addressed to:

DHEC Bureau of Laboratories Attn. Specimen Accessioning 8231 Parklane Road Columbia, SC 29223

4. Ship by state courier or first class US Mail. No additional labeling is required on the outside of the envelope. The slides are not considered infectious materials.

#### **Shipping Newborn Screening Blood Spots**

- 1. Allow blood spots to **AIR DRY** thoroughly on a level non-absorbent surface such as a plastic coated test tube rack at least 4 hours at room temperature.
- 2. Place **dried** filter paper form(s) into the provided mailing envelope. Mail the specimen within 24 hours. No additional labeling is required on the outside of the envelope. The dried blood spots cannot leak or spill.
- 3. Ship by state courier or first class US Mail. No additional labeling is required on the outside of the envelope.

## Shipping Infectious Substances and Diagnostic Specimens

The International Air Transport Association (IATA) classification system for shipping infectious substances changed on January 1, 2005. There were also some changes in the marking and labeling requirements. The US Department of Transportation (DOT) published a proposed rule on May 19, 2005 to harmonize the DOT regulations with the changes made by IATA (United Nations Recommendations). The US Postal Service plans to bring their regulations into alignment with IATA; proposed changes will be published in the spring of 2006. Risk groups are no longer used to determine the proper shipping category for infectious substances. The following definitions are now used.

#### **IATA Definitions:**

**CULTURES:** Cultures are the result of a process by which pathogens are intentionally propagated. This definition does not include human or animal patient specimens as defined in 3.6.2.1.4.

**DANGEROUS GOODS:** Articles or substances which are capable of posing a risk to health, safety, property or the environment and which are shown in the list of dangerous goods in theses Regulations or which are classified according to the Regulations.

**INFECTIOUS SUBSTANCES**: Substances which are known or are reasonably expected to contain pathogens. Pathogens are defined as microorganisms (including bacteria, viruses, rickettsiae, parasites, fungi) and other agents such as prions, which can cause disease in humans or animals.

**PACKING:** The art and operation by which articles or substances are enveloped in wrappings and/or enclosed in packaging or otherwise secured.

**PATIENT SPECIMENS:** Patient specimens are those human and animal materials, collected directly from humans or animals, including, but not limited to, excreta, secreta, blood and its components, tissue and tissue fluid swabs, and body parts being transported for purposes such as research, diagnosis, investigational activities, disease treatment and prevention.

**PROPER SHIPPING NAME:** The name to be used to describe a particular article or substance in all shipping documents and notifications and, where appropriate, on packaging.

**SHIPMENT**: The specific movement of a consignment from origin to destination.

**UN NUMBER**: The four digit number assigned by the United Nations Committee of Experts on the Transport of Dangerous Goods to identify a substance or a particular group of substances. (The prefix "UN" must always be used in conjunction with these numbers.)

#### **Classifying Infectious Substances**

Infectious substances are divided into 2 categories – A and B.

**Category A**: An infectious substance which is transported in a form that, when exposure to it occurs, is capable of causing permanent disability, life-threatening or fatal disease in otherwise healthy humans or animals. Indicative examples of substances that meet these criteria are given in Table 3.6.D.

**Category B**: An infectious substance which does not meet the criteria for inclusion in Category A. Infectious substances in Category B must be assigned to UN 3373.

As a general rule, all cultures will be in category A and most body fluids and tissue will be in category B. A swab placed in a genprobe bottle would not meet the IATA definition of a culture and would be shipped as a diagnostic specimen.

Table 3.6.D (pages 4 & 5) was developed as a guidance document to give examples of infectious agents that should be classified as category A regardless of the type of specimen.

**Note**: This table is not exhaustive. Infectious substances, including new or emerging pathogens, which do not appear in the table but which meet the same criteria must be assigned to category A.

# **Table 3.6.D from IATA Dangerous Goods Regulations** Indicative Examples of Infectious Substances Included in Category A in Any Form Unless Otherwise Indicted (3.6.2.2.2.1) (Updated 1-1-2006)

UN Number and	(5.0.2.2.2.1) (opalica 1 1 2000)					
<b>Proper Shipping Name</b>	Micro-organism					
UN 2814	Bacillus anthracis (cultures only)					
Infectious substance	Brucella abortus (cultures only)					
affecting humans	Brucella melitensis (cultures only)					
	Brucella suis (cultures only)					
	Burkholderia mallei - Pseudomonas mallei - Glanders (cultures only)					
	Burkholderia pseudomallei - Pseudomonas pseudomallei (cultures only)					
	Chlamydia psittaci - avian strains (cultures only)					
	Clostridium botulinum (cultures only)					
	Coccidioides immitis (cultures only)					
	Coxiella burnetii (cultures only)					
	Crimean-Congo hemorrhagic fever virus					
	Dengue virus (cultures only)					
	Eastern equine encephalitis virus (cultures only)					
	Escherichia coli, verotoxigenic (cultures only)					
	Ebola virus					
	Flexal virus					
	Francisella tularensis (cultures only)					
	Guanarito virus					
	Hantaan virus					
	Hantavirus causing hemorrhagic fever with renal syndrome					
	Hendra virus					
	Hepatitis B virus (cultures only)					
	Herpes B virus (cultures only)					
	Human immunodeficiency virus (cultures only)					
	Highly pathogenic avian influenza virus (cultures only)					
	Japanese Encephalitis virus (cultures only)					
	Junin virus					
	Kyasanur Forest disease virus					
	Lassa virus					
	Machupo virus					
	Marburg virus					
	Monkeypox virus					
	Mycobacterium tuberculosis (cultures only)					
	Nipah virus					
	Omsk hemorrhagic fever virus					
	Poliovirus (cultures only)					
	Rabies virus (cultures only)					
	Rickettsia prowazekii (cultures only)					
	Rickettsia rickettsii (cultures only)					
	Rift Valley fever virus (cultures only)					
	Russian spring-summer encephalitis virus (cultures only)					

	Sabia virus						
	Shigella dysenteriae type 1 (cultures only)						
	Tick-borne encephalitis virus (cultures only)						
	Variola virus						
	Venezuelan equine encephalitis virus (cultures only)						
	West Nile virus (cultures only)						
	Yellow fever virus (cultures only)						
	Yersinia pestis (cultures only)						
UN 2900	African swine fever virus (cultures only)						
Infectious substances	Avian paramyxovirus Type 1 - Newcastle disease virus (cultures only)						
affecting animals	Classical swine fever virus (cultures only)						
	Foot and mouth disease virus (cultures only)						
	Goatpox virus (cultures only)						
	Lumpy skin disease virus (cultures only)						
	Mycoplasma mycoides - Contagious bovine pleuropneumonia (cultures						
	only)						
	Peste des petits ruminants virus (cultures only)						
	Rinderpest virus (cultures only)						
	Sheep-pox virus (cultures only)						
	Swine vesicular disease virus (cultures only)						
	Vesicular stomatitis virus (cultures only)						

# Examples of shipping categories

Material	Infectious Substance, category A	Infectious Substance, category B
Culture of HIV virus	X	
Tube of blood from a HIV + person		X
Tube of blood from a person infected with Bacillus anthracis		X

## **Proper Shipping Names and UN Numbers**

Once an infectious material has been classified, then the proper shipping name must be determined. The proper shipping name is required on the outer packaging. The UN number must also be on the outside packaging for infectious substances, category A. If transport is by air, the UN number must be on the outside packaging for infectious substances, category B (diagnostic specimens). The table below lists the proper shipping names and UN numbers needed to ship infectious substances and diagnostic specimens.

#### **Proper Shipping Names**

(from IATA Dangerous Goods Regulations, effective 1 January – 31 December 2006, 4 2 List of Dangerous Goods)

Classification	Proper shipping name	UN number
Infectious substance,	Infectious substance, affecting	UN 2814
Category A (infects humans	humans	
& may infect animals)		
Infectious substance,	Infectious substance, affecting	UN 2900
Category A (only infects	animals	
animals)		
Infectious substance,	Diagnostic Specimen or	UN 3373
category B	Clinical Specimen or	
	Biological Substance, Category B	
	[Note: From 1 January 2007, it is	
	anticipated that the use of the	
	shipping names Diagnostic	
	specimens and Clinical specimens	
	will no longer be permitted.]	

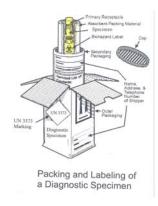
# **Packing Infectious Substances for Transport**

All packaging is based on a "triple" receptacle shipper.

- Infectious substances, category A, must be packaged to meet packing instruction **602**.
- Infectious substances, category B (Diagnostic specimens) must be packaged to meet packing instruction **650**.

#### A primary receptacle is the container (e.g., tube vial, bottle) that holds the specimen.

- The primary receptacle must be securely sealed and leak proof (screw top tubes must have a piece of waterproof tape around the top to prevent the top from coming loose in transit).
- The primary receptacle must be surrounded by absorbent material capable of taking up the entire liquid contents.
- The primary receptacle must be packed in the secondary receptacle in such a way that it will not break.



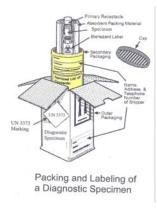
• IATA regulations allow 1 liter in a primary receptacle for diagnostic specimens. The outer packaging must not contain more than 4 liters.

**NOTE**: Most DHEC shippers are designed for a **maximum of 50 ml** of liquid diagnostic specimens. Remember, there must always be adequate absorbent materials to absorb the amount of liquid in a primary receptacle.

# <u>Secondary packaging</u> is the receptacle into which a primary receptacle and the absorbent and cushioning material are placed.

- The secondary packaging must be leak proof and securely sealed.
- The secondary packaging must be placed in the outer packaging so that it does not move.

Note: A ziplock biohazard bag may serve as the secondary receptacle for a diagnostic specimen if transport is by ground with the state courier system.



#### **Itemized List of Contents**

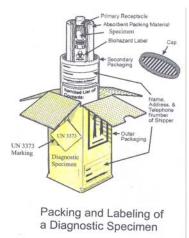
- An itemized list of contents is required.
- The itemized list is placed OUTSIDE the secondary container. The laboratory form should also be placed OUTSIDE the secondary container.
- DO NOT place documents inside the secondary container.

#### Itemized List used by the Bureau of Laboratories

Shipped from:	SC DHEC Bureau of Laboratories 8231 Parklane Road Columbia, SC 29223 Emergency Contacts: Connie Gray or Dr. Arthur Wozniak Emergency Telephone: (803) 896-0800	
Shipped to:		
Shipping Temper: ambient cold packs dry ice	Next day delivery required  No Yes	
temized List of C	ontents (list name of organism when known, list amount)	

# <u>Outer packaging</u> is the receptacle into which the secondary receptacle, along with cushioning materials, are placed.

- The outer packaging must be rigid (effective 1-1-2005).
- The outer packaging bears the addressing information along with all required markings and labels. The full name and address of the shipper and the consignee must be on the outside packaging. The outside packaging must also have the name and telephone number of a person who is knowledgeable about the contents of the shipment. This is important emergency information in the event an exposure occurs during shipping.



- For air transport, at least one surface of the outer packaging must have a minimum dimension of 4 inches x 4 inches.
- For air transport of diagnostic specimens, a UN 3373 marking must be on the outside receptacle. The words "Diagnostic Specimen" must be marked on the outer package adjacent to the diamond-shaped UN 3373 marking.

**Note** - Only the words "Diagnostic Specimen" are required for packages in the state courier system and the US Postal Service at this time.

**Note - Do not** place biohazard stickers on the outside container. The biohazard marking should be on the secondary receptacle and may be on the primary receptacle.

• If a "Shippers' Declaration for Dangerous Goods" is required, the document is attached to the top of the outside packaging.

For diagnostic specimens, the completed package must be capable of successfully passing a drop test of 1.2 meters. If transport is by air, the completed package must pass a pressure test.

Additional Requirements for Infectious Substance, Category A
Packaging

- Packaging must be UN certified (this means the packaging unit has passed drop, impact and pressure tests)
- The UN Certification number must be printed on the outside container.
- UN Certified Packaging must be used as a complete shipping package as received from the manufacturer. Substitution of parts of the packaging with other manufacturer's shipping materials is not allowed.
- Maximum quantity per shipper is 50 ml or 50 grams on passenger aircraft and 4 liters on cargo aircraft.
- The Class 6 Infectious Substance label must be on the outside packaging.
- The proper shipping name and UN number must be on the outside packaging. Adjacent to this information the net quantity of infectious substance in the package must be shown. Effective January 1, 2005, for security purposes, the name of the organism is no longer required on the outside packaging. However, the name of the organism is still required on the "Shipper's Declaration For Dangerous Goods".
- Documentation the material was received (email, USPS return receipt, tracking number showing receipt, etc.) along with a copy of the "Shippers' Declaration for Dangerous Goods must be kept for 375 days.
   NOTE: Federal Aviation Administration (FAA) Inspectors refer to this documentation as your 375 day file.
- Most packaging for cultures of infectious substances is designed to hold screw-top tubes. If possible, ship the culture on an agar slant in a screw-top tube. Tape around the screw top with autoclave tape to prevent the top from working loose

during shipment. If culture plates must be shipped, ensure the packaging set-up will accommodate and protect a culture plate. Culture plates should always be taped closed and placed in a zip lock bag as the first step in packaging.

## **Shippers Declaration of Dangerous Goods**

The "Shipper's Declaration For Dangerous Goods" is a legal document. If it is not 100% correct, it is **WRONG** and your package will be refused for shipment and returned.

- A "Shippers Declaration of Dangerous Goods" is **not** required for diagnostic specimens.
- A "Shippers Declaration of Dangerous Goods" is required for infectious substances, category A by commercial carriers.



**Note** – The state courier does not require a "Shipper's Declaration for Dangerous Goods". This is one very good reason to use the state courier system.

- The document must be attached to the top of the package in a ziplock bag
- The document must be completed in **triplicate**, each as an original, with the red stripe down each side of the paper. Two copies are given to the transporter and one copy is kept for your files.

**Note** - The format of the "Shippers Declaration For Dangerous Goods" will change on January 1, 2007. In the "Nature and Quantity of Dangerous Goods" section, the UN number will be the first column. The revised document may be used now, but will be required on January 1, 2007.

The Shippers Declaration For Dangerous Goods may be completed on line at <a href="http://www.fedex.com/us/services/pdf/ShippersDecColumnsColorPrinter.pdf?link=4">http://www.fedex.com/us/services/pdf/ShippersDecColumnsColorPrinter.pdf?link=4</a> and printed on a color printer.

Examples of completed "Shippers' Declaration for Dangerous Goods" are found at the end of this document.

## **Shipping Temperatures**

Check the test section in the *Bureau of Laboratories Services Guide*, if unsure of temperature requirements for the infectious substance being shipped.

- If the specimen must be shipped cold, but not frozen, use cold packs. Ice will melt
  and leak during shipping.
   [NOTE: All diagnostic specimens shipped for PCR testing should be shipped
  cold.]
- If the specimen must be shipped frozen, additional labeling is required for dry ice.

## Labeling and Marking required for Dry Ice

- Class 9 DOT label
- DRY ICE UN 1845
- The amount of dry ice in the package in kilograms must be shown. One pound equals 2.2 kg.
- Dry ice must also be listed on the "Shippers Declaration For Dangerous Goods"





# These shippers are also available for use in the State Courier system and USPS



Shipper for mycobacteriology specimen



Enteric Shipper, contains Cary-Blair transport medium



Shipper for parasitology stool sample

## **Bioterrorism Specimens and Cultures**

Prior notification is requested for specimens and/or cultures being sent for "rule out/rule in" testing for bioterrorism agents.

Please notify **Dr. Jennifer Meredith**, **803-896-0870**, before shipping these diagnostic specimens or cultures.

Alternate: Dr. Arthur Wozniak 803-896-0965

# The shipping address for Bureau of Laboratories is:

Bureau of Laboratories Business hours are 8:00 AM to 4:30 PM

8231 Parklane Road Monday through Friday, except for state holidays

Columbia, SC 29223

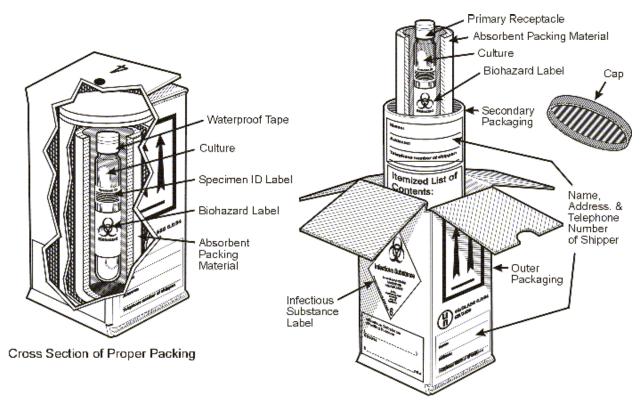
24/7 telephone number 803-896-0800

# For questions on shipping information, contact:

Connie Gray, Safety Officer SC DHEC Bureau of Laboratories 803-896-0956 FAX 803-896-0983

#### **Important Points to Remember**

- The shipper is responsible for the infectious substance package until it is in the hands of the recipient. **Proper packaging, marking and labeling is the shipper's responsibility.**
- Commercial carriers (Federal Express, Airborne Express, etc.) may have additional requirements which are unique to their company. If you have any questions on packaging, marking, labeling, or documentation, always check with the commercial carrier you plan to use.
- Make sure that the correct marking and labeling information is on the outside packaging.
- Do not put laboratory forms inside the secondary container with the specimen.
- The outside packaging should have the name and telephone number of a person who is knowledgeable about the contents of the shipment. This is important emergency information in the event an exposure occurs during shipping.
- Do NOT put biohazard labels on the outside packaging. The biohazard label should be on the secondary receptacle.
- Do NOT use excessive tape to close the outside container. One piece of clear packaging tape should be adequate.
- Do NOT cover or deface any label or marking. A commercial transporter will not accept the package.
- Seal the package with clear shipping tape. Cut the tape to open the package. Pulling the tape off often defaces the markings and labels on the outside packaging.
- If an overpack with dry ice is used, a good rule of thumb is to add at least 6 pounds per 24-hour period. The US Postal Service limits the amount of dry ice per package to 5 pounds; therefore if more than 5 pounds of dry ice is needed, another transporter must be used.
- Employees shipping infectious substances must be trained on proper packaging and labeling. Training must be documented. Retraining is required when the regulations change or every three years. Some transporters will require a written certification of the training.
- If the infectious material is sent through the United States Postal Service, the package must be sent by Priority Mail or First Class Mail, using Registered Service.



# Packing and Labeling of Infectious Substances Category A

# Transporting Infectious Substances in a private or DHEC vehicle

Secure the properly packed and labeled infectious substance package in the vehicle as far away as possible from the driver, preferably in the trunk if available. If the vehicle is involved in an accident, the package should not be thrown around the vehicle. If there is an accident, emergency responders need to know that infectious substances are in the package.

#### **References for information in this document:**

IATA Dangerous Goods Regulations, 47<sup>th</sup> edition, effective January 1, 2006 to December 31, 2006

United States Postal Service, Domestic Mail Manual

Centers for Disease Control and Prevention, Guidelines for the Shipment of Dried Blood Spot Specimens.

#### SHIPPER'S DECLARATION FOR DANGEROUS GOODS

(Provide at least three copies to FedEx Express)

Shipper Air Waybill No SC DHEC Bureau of Laboratories 8231 Parklane Road Page 1 of 1 Pages Columbia, SC 29223 Shipper's Reference Number Responsibel party Connie Gray or Dr. Arthur Wozniak 1-803-896-0800 Consignee CDC 1234 Clifton Road Atlanta, GA Two completed and signed copies of this Declaration must be handed to the operator. WARNING Failure to comply in all respects with the applicable TRANSPORT DETAILS Dangerous Goods Regulations may be in breach This shipment is within the Airport of Departure of the applicable law, subject to legal penalties. limitations prescribed for This Declaration must not, in any circumstances, Columbia, SC (delete non-applicable) be completed and/or signed by a consolidator, a PASSENGER AND CARGO AIRCRAFT forwarder or an IATA cargo agent. CARGO AIRGEAFT ONLY Airport of Destination Shipment type: (delete non-applicable)
NON-RADIOACTIVE Atlanta, GA

NATURE AND QUANTITY OF DANGEROL	00000

Dangerous Goods Identification							
Proper Shipping Name	Class or Divi- sion	UN or ID No.	Pack- ing Group	Subsi- diary Risk	Quantity and Type of packing	Packing Inst.	Authorization
Infectious substance, affecting humans (Hepatitis B virus culture)	6. 2	UN2814			50 mls packed in one Fibreboard Box	602	

#### Additional Handling Information

I declare that all of the applicable air transport requirements have been met.

Emergency Telephone Number 803-896-0800

I hereby declare that the contents of this consignment are fully and accurately described above by the proper shipping name, and are classified, packaged, marked, and labelled/placarded, and are in all respects in proper condition for transport according to applicable international and national governmental regulations.

Name/Title of Signatory Carlton Atkinson, Material Logistics Manager Place and Date Columbia, SC 9-15-03 Signature

(see warning above) Couldon Atkinson

IF ACCEPTABLE FOR PASSENGER AIRCRAFT, THIS SHIPMENT CONTAINS RADIOACTIVE MATERIAL INTENDED FOR USE IN, OR INCIDENT TO, RESEARCH, MEDICAL DIAGNOSIS, OR TREATMENT

#### SHIPPER'S DECLARATION FOR DANGEROUS GOODS

(Provide at least three copies to FedEx Express)

Shipper
SC DHEC Bureau of Laboratories
8231 Parklane Road
Columbia, SC 29223
Responsibel party Connie Gray or Dr. Arthur Wozniak
1-803-896-0800

Air Waybill No

Page 1 of 1 Pages Shipper's Reference Number

Consignee

CDC

1234 Clifton Road Atlanta, GA Fed Express

Two completed and signed copies of this Declaration must be handed to the operator.

#### WARNING

TRANSPORT DETAILS

This shipment is within the limitations prescribed for (delete non-applicable) Airport of Departure

Columbia, SC

Failure to comply in all respects with the applicable Dangerous Goods Regulations may be in breach of the applicable law, subject to legal penalties. This Declaration must not, in any circumstances, be completed and/or signed by a consolidator, a forwarder or an IATA cargo agent.

PASSENGER AND CARGO AIRCRAFT

Airport of Destination

Atlanta, GA

Shipment type: (delete non-applicable)
NON-RADIOACTIVE RADIOACTIVE

#### NATURE AND QUANTITY OF DANGEROUS GOODS

Dangerous Goods Identification							
Proper Shipping Name	Class or Divi- sion	UN or ID No.	Pack- ing Group	Subsi- diary Risk	Quantity and Type of packing	Packing Inst.	Authorization
Infectious substance, affecting humans (Hepatitis B virus culture)	6. 2	UN2814			50 mls packed in one Fibreboard Box	602	
Dry Ice	9	UN1845	Ш		3 kg Overpack used	904	

Additional Handling Information

I declare that all of the applicable air transport requirements have been met.

Emergency Telephone Number 803-896-0800

I hereby declare that the contents of this consignment are fully and accurately described above by the proper shipping name, and are classified, packaged, marked, and labelled/placarded, and are in all respects in proper condition for transport according to applicable international and national governmental regulations.

Name/Title of Signatory
Carlton Atkinson, Material Logistics Manager
Place and Date
Columbia, SC 9-15-03

Signature

(see warning above) Carbon Atkinson

IF ACCEPTABLE FOR PASSENGER AIRCRAFT, THIS SHIPMENT CONTAINS RADIOACTIVE MATERIAL INTENDED FOR USE IN, OR INCIDENT TO, RESEARCH, MEDICAL DIAGNOSIS, OR TREATMENT